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EXAMINER

KUBELIK, ANNE R

ART UNIT

PAPER NUMBER

1638

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Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Application No.

10/073,930

Applicant(s)

TAURICK, GARY

Examiner

Anne R. Kubelik

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☐ Responsive to communication(s) filed on \_\_\_\_.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 1-32 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-32 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

## Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s) \_\_\_\_.
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) \_\_\_\_ 6) ☐ Other: \_\_\_\_\_

### **DETAILED ACTION**

1. Claims 1-32 are pending.

#### ***Claim Objections***

2. Claims 1, 7, 9 and 18 are objected to for the inclusion of a blank line where the ATCC Accession number should be.
3. Claims 29-31 are objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form. Claims 30-31 are drawn to plants, further comprising a single gene conversion. These plants are broader than the plants of parent claim 5, which does not have a single gene conversion, but instead have all of the morphological and physiological characteristics of a plant produced by growing 8D-5079 seed.
4. Claims 8, 18 and 20 are objected to because of the following informalities:  
  
Claim 8 lacks a period at the end of the claim and there should be an --and-- after "cotyledons," in line 4.  
  
Claims 18 and 20 need an --and-- at the end of lines 4 and 5, respectively.

#### ***Claim Rejections - 35 USC § 112***

5. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

6. Claims 6, 11-13, 15-17 and 19-32 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter that was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The claims are drawn to hybrid cucumber seeds, plants produced from said seed, and seed produced from said plants, wherein one of the parents is 8D-5079 and the other parent is not specified. The hybrid plants are not defined by genomic structure or by phenotypic characteristics, and it is unclear what characteristics of 8D-5079 would be present in the claimed hybrid seed and plants. Due to segregation and recombination of the parent genomes during meiosis, one cannot predict what traits or combinations of traits will be passed on to any given hybrid seed and plant. In fact, *each* hybrid seed derived from a cross between two genetically distinct parent plants will have unique combinations of characteristics. Therefore, the claimed invention lacks an adequate written description.

The claims are also drawn to cucumber plants and methods of producing cucumber plants that involve an indeterminate number of generations and parent plants or of introduced single gene conversions and transgenes of unknown function and number, wherein it remains unclear what the identity of the plants in each of the steps would be, much less what the resultant product plant would be. Neither the plants required by each of the steps, nor the plants that are produced by the process are defined by genomic structure or by phenotypic characteristics, and therefore, the claimed invention lacks an adequate written description.

See *Univ. of California v. Eli Lilly*, 119 F.3d 1559, 43 USPQ 2d 1405 (Fed. Cir. 1997) , where it states:

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[a] written description of an invention involving a chemical genus, like a description of a chemical species, "requires a precise definition, such as by structure, formula, [or] chemical name," of the claimed subject matter sufficient to distinguish it from other materials.

See also *J.E.M. Ag Supply Inc. v. Pioneer Hi-Bred International Inc.*, 60 USPQ2d 1865

(US Sup Ct 2001) at pg 2 of the decision, where it states:

The description requirement for plants includes a deposit of biological material, for example seeds, and mandates that such material be accessible to the public. See 37 CFR §§1.801–1.809 (2001); see also App. 39 (seed deposits for U. S. Patent No. 5,491,295).

Thus, written description of the progeny seed and plants can only be met by deposit of said seed and plants.

Therefore, given the lack of written description in the specification with regard to the structural and physical characteristics of the claimed compositions, and given the high level of unpredictability in this art, one skilled in the art would not have been in possession of the genus claimed at the time this application was filed.

7. Claims 6 and 29-31 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter that was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

The claims are broadly drawn to a plant having all of the morphological and physiological characteristics of a plant produced by growing 8D-5079 seed, further comprising a single gene conversion.

The instant specification fails to provide guidance for making a single gene conversion. No guidance is provided for introgression of any trait from a multitude of non-disclosed and uncharacterized parentals into the plants, wherein said introgression results in successful expression of the desired trait but does not interfere with the expression of the remaining traits

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such that essentially all of the desired morphological and physiological characteristics of the inbred are recovered in addition to the single gene (as required in the definition in ¶0033).

With respect to single gene conversions, it is unpredictable whether the gene or genes responsible for conferring a phenotype in one plant background may be introgressed into the genetic background of a different plant to confer a desired phenotype in the plant. Hunsperger et al (1996, US Patent 5,523,520) teach that introgression of a gene in one genetic background into any other plant of the same species, as performed by sexual hybridization, is unpredictable into producing a single gene conversion plant with a desired trait (column 3, lines 26-46). In particular, they teach that a gene conferring miniature plant stature, which was in one Petunia cultivar, does not confer the miniature phenotype when introgressed into the genome of other petunia cultivars (column 3, lines 40-41). Kraft et al (2000, Theor. Applied. Genet. 101:323-326) teach that linkage disequilibrium effects and linkage drag prevent the making of plants comprising a single gene conversion and that such effects are unpredictably genotype specific and loci-dependent in nature (pg 323). Kraft et al teach that linkage disequilibrium is created in breeding materials when several lines become fixed for a given set of alleles at a number of different loci, and that very little is typically known about the plant breeding materials which contributes to the unpredictability of the effect. Lastly, Eshed et al (1996, Genetics 143:1807-1817) teach that in plants, epistatic genetic interactions from various genetic components comprising contributions from different genomes may affect quantitative traits in a genetically complex and less than additive fashion (pg 1815).

Lastly, the specification fails to provide guidance for any genes that confer sex determination, or improved nutritional or agronomic quality, or for any dominant or recessive

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alleles.

Given the claim breath, unpredictability, and lack of guidance as discussed above, undue experimentation would have been required by one skilled in the art to develop and evaluate plants having all of the morphological and physiological characteristics of a plant produced by growing 8D-5079 seed, wherein the plants further comprise a single gene conversion.

8. Claims 1-32 are rejected under 35 USC 112, first paragraph, as containing subject matter that was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

Since the seed claimed is essential to the claimed invention, it must be obtainable by a repeatable method set forth in the specification or otherwise be readily available to the public. If a seed is not so obtainable or available, a deposit thereof may satisfy the requirements of 35 U.S.C. 112. The specification does not disclose a repeatable process to obtain the exact same seed in each occurrence and it is not apparent if such a seed is readily available to the public. It is noted that Applicant intends to deposit seeds for 8D-5079 at the ATCC, but there is no indication that the seeds have been deposited and there is no indication in the specification as to public availability. If the deposit of these seeds is made under the terms of the Budapest Treaty, then an affidavit or declaration by the Applicant, or a statement by an attorney of record over his or her signature and registration number, stating that the seeds will be irrevocably and without restriction or condition released to the public upon the issuance of a patent would satisfy the deposit requirement made herein. A minimum deposit of 2500 seeds is considered sufficient in the ordinary case to assure availability through the period for which a deposit must be maintained.

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If the deposit has not been made under the Budapest Treaty, then in order to certify that the deposit, meets the criteria set forth in 37 CFR 1.801-1.809, Applicant may provide assurance of compliance by an affidavit or declaration, or by a statement by an attorney of record over his or her signature and registration number showing that

(a) during the pendency of the application, access to the invention will be afforded to the Commissioner upon request;

(b) all restrictions upon availability to the public will be irrevocably removed upon granting of the patent;

(c) the deposit will be maintained in a public depository for a period of 30 years or 5 years after the last request or for the enforceable life of the patent, whichever is longer;

(d) the viability of the biological material at the time of deposit will be tested (see 37 CFR 1.807); and

(e) the deposit will be replaced if it should ever become inviable.

9. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

10. Claims 1-24 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter that Applicant regards as the invention. Dependent claims are included in all rejections.

Claims 1, 7, 9 and 18 are indefinite in their recitation of "ATCC Accession No. \_\_\_\_\_", because the ATCC Accession No. is missing.

Claim 1 is indefinite in its recitation of "a cucumber seed designated 8D-5079", claims 7 and 18 are indefinite in their recitation of "cucumber line 8D-5079", claim 7 is indefinite in its recitation of "cucumber plant of variety 8D-5079", claim 9 is indefinite in its recitation of "inbred cucumber line 8D-5079", claims 18-23 are indefinite in their recitation of "8D-5079-derived", claims 19, 21, 23, 28 and 32 are indefinite in their recitation of "8D-5079 traits", and claims 25 is indefinite in its recitation of "cucumber plant of the line 8D-5079", given that a name does not clearly identify the claimed cucumber cultivar and seed, and does not set forth the metes and bounds of the claimed invention. Since the name 8D-5079 is not known in the art, the



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use of said name does not carry art recognized limitations as to the specific characteristics or essential characteristics that are associated with that denomination. In addition, the name appears to be arbitrary, and the specific characteristics associated therewith could be modified, as there is no written description of the cucumber plant that encompasses all of its traits. Amending the claims to recite the ATCC deposit number would overcome the rejection.

Claim 6 is indefinite in its recitation of “wherein said plant is male-sterile”. The specification teaches that 8D-5079 is “an excellent pollen parent line in crosses for producing first generation (F<sub>1</sub>) hybrid cucumbers” (paragraph 0047). Thus, a plant having all of the morphological and physiological characteristics of a plant produced by growing 8D-5079 seed would be male fertile.

Claim 7 is indefinite in its recitation of “capable of expressing”. It is suggested that the phrase be replaced with --having--.

Claim 8 is indefinite is its recitation of “The tissue culture of claim 7, selected from the group of protoplast and calli, wherein the regenerable cells”. First, “protoplast” in line 1 should be plural. Second, does Applicant mean that the tissue culture is in the form of protoplasts or calli? It is unclear what “wherein the regenerable cells” modifies - the calli or the tissue culture. It is particularly confusing because callus and protoplasts are among the list of regenerable cells. Does the claim mean that of all the regenerable cells of the list, the claim is only drawn to tissue culture derived from protoplasts and calli?

Claim 9 is indefinite is its recitation of “capable of expressing”. It is not clear if the plant actually does express all these characteristics. It is also not clear if it is the plant or the tissue culture that is capable of expressing.

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Claim 14 is indefinite in its recitation of ‘another, different’. It is unclear if Applicant simply means that the plant is a plant other than the plant according to claim 2 or if two different plants (the another plant and the different plant) are used.

Claim 14 lacks antecedent basis for the limitation “an inbred plant according to claim 2” in lines 1-2, as claim 2 is only drawn to a cucumber plant.

In claim 18, part (b) and claim 20, part (d), the phrase “under plant growth conditions” is meaningless because Applicant has not defined appropriate plant growth conditions. The phrase should be deleted.

Claims 19, 23, 28 and 32 are indefinite in their recitation of “extended yield pattern”, since this is a relative term, it is unclear how it is measured or what standard it is based on, and the specification fails to define or clarify the use of this term. Therefore, the characteristics of the claimed plant remain unclear.

Claims 19, 23, 28 and 32 are indefinite in their recitation of “very dark green skin color”, since this is a relative term, it is unclear how it is measured or what standard it is based on, and the specification fails to define or clarify the use of this term. Therefore, the characteristics of the claimed plant remain unclear.

Claims 19, 23, 28 and 32 are indefinite in their recitation of “reduced blossom end striping”, since this is a relative term, it is unclear how it is measured or what standard it is based on, and the specification fails to define or clarify the use of this term. Therefore, the characteristics of the claimed plant remain unclear.

Claims 19, 23, 28 and 32 are indefinite in their recitation of “small seed cavity”, since this is a relative term, it is unclear how it is measured or what standard it is based on, and the

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specification fails to define or clarify the use of this term. Therefore, the characteristics of the claimed plant remain unclear.

Claims 19, 23, 28 and 32 are indefinite in their recitation of “small blossom end”, since this is a relative term, it is unclear how it is measured or what standard it is based on, and the specification fails to define or clarify the use of this term. Therefore, the characteristics of the claimed plant remain unclear.

Claims 19, 23, 28 and 32 are indefinite in their recitation of “very high yield”, since this is a relative term, it is unclear how it is measured or what standard it is based on, and the specification fails to define or clarify the use of this term. Therefore, the characteristics of the claimed plant remain unclear.

Claims 19, 23, 28 and 32 are indefinite in their recitation of “adapted to”, since it is unclear what it means for the plant to be “adapted” to any one of the regions. The specification fails to define or clarify the use of this term. Therefore, the characteristics of the claimed plant remain unclear.

Claims 19, 23, 28 and 32 are indefinite in their recitation of “used to produce hybrids having a maturity between 55 and 62 days” in lines 7-8, as this is a use of a plant, not a trait of the plant itself.

In claim 22, the method step “utilizing plant tissue culture methods to derive progeny” is indefinite. Applicant must amend the claim to clearly define the additional method steps.

Claims 24-26 are indefinite in their recitation of a cucumber plant containing “one or more transgenes”, since it is unclear how many new traits the claimed plant would exhibit, and it remains unclear what the phenotype of the claimed plant would be.

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Claim 23 is indefinite because there are no clear positive method steps. The method step “employing a cucumber plant” in line 2 does not recite clearly defined positive method steps. The improper Markush group “wherein plant breeding techniques are selected from the group consisting of ...” renders the claim indefinite, since it is unclear how many techniques would be used and in what combinations. Again, the method steps are not clearly defined. For example, it is uncertain for each of the recited breeding techniques what steps they would be comprised of, how many generations of crosses would be incorporated in the method, and what parent plants would be used for each cross.

Claims 30-31 lack antecedent basis for the limitation “the single gene conversion cucumber plant of claim 29” as claim 29 is drawn to a cucumber plant.

The phrase “improved nutritional and agronomic quality” in claim 31 is a relative term that renders the claim indefinite. The phrase “improved nutritional and agronomic quality” is not defined by the claim, the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention. Improved relative to what? Improved in what manner or by whose definition? For example, one person may consider a sweeter fruit improved and another a less sweet fruit improved.

In claim 32, line 2, it is unclear if the second “cucumber plant” refers to the cucumber plant in line 1 or the first cucumber plant mentioned in line 2.

***Claim Rejections - 35 USC § 102 - 35 USC § 103***

11. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless --

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

12. The following is a quotation of 35 U.S.C. 103(a), which forms the basis for all obviousness rejections set forth in this Office action:

- (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

13. Claims 11-13, 15-17 and 19-32 are rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103 as obvious over Walters et al (1997, HortScience 32:1301-1303).

Applicant has claimed plants derived from 8D-5079 cucumber after one or more crosses and using unspecified second parents and methods of making those plants. In addition, some of the claims specify that at least two designated characteristics would be present in the claimed cucumber. However, the claimed plants and seeds are indistinguishable from the prior art cucumber cultivars "Lucia", "Manteo", "Shelby", and their hybrid progeny, given that each has high yield and dark green skin color, for example. Alternatively, if the claimed plants and seeds of the instant invention are not identical to cucumber cultivars "Lucia", "Manteo", "Shelby", and their hybrid progeny, then it appears that "Lucia", "Manteo", "Shelby", and their hybrid progeny only differ from the claimed plants and seeds due to minor morphological variation, wherein said minor morphological variation would be expected to occur in different progeny of the same

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cultivar, and wherein said minor morphological variation would not confer a patentable distinction to 8D-5079-derived plants. Similarly, the methods of crossing 8D-5079-derived cucumber would be the same as the methods of crossing prior art cucumber cultivars “Lucia”, “Manteo”, “Shelby”, and their hybrid progeny. Lastly, 8D-5079 cucumber into which has been transformed an unspecified number of unidentified transgenes would be indistinguishable from the prior art cucumber cultivars “Lucia”, “Manteo”, and “Shelby” or their hybrid progeny. Thus the claimed invention was *prima facie* obvious as a whole to one of ordinary skill in the art at the time it was made, if not anticipated by “Lucia”, “Manteo”, “Shelby”, and their hybrid progeny, and methods of their use.

14. Claims 11-13, 15-17 and 19-32 are rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103 as obvious over Wehner (1998, Hortscience 33:168-170).

Applicant has claimed plants derived from 8D-5079 cucumber after one or more crosses and using unspecified second parents and methods of making those plants. In addition, some of the claims specify that at least two designated characteristics would be present in the claimed cucumber. However, the claimed plants and seeds are indistinguishable from the prior art cucumber populations NCWBS, NCMBS, and NCES1, given that each has high yield and dark green skin color, for example. Alternatively, if the claimed plants and seeds of the instant invention are not identical to cucumber populations NCWBS, NCMBS, and NCES1, then it appears that cucumber populations NCWBS, NCMBS, and NCES1 only differ from the claimed plants and seeds due to minor morphological variation, wherein said minor morphological variation would be expected to occur in different progeny of the same cultivar, and wherein said minor morphological variation would not confer a patentable distinction to 8D-5079-derived

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plants. Similarly, the methods of crossing 8D-5079-derived cucumber would be the same as the methods of crossing prior art cucumber populations NCWBS, NCMBS, and NCES1. Lastly, 8D-5079 cucumber into which has been transformed an unspecified number of unidentified transgenes would be indistinguishable from the prior art cucumber populations NCWBS, NCMBS, and NCES1. Thus the claimed invention was *prima facie* obvious as a whole to one of ordinary skill in the art at the time it was made, if not anticipated by populations NCWBS, NCMBS, and NCES1 and methods of their use.

15. Claims 1-10, 14 and 18 are free of the prior art, given the failure of the prior art to teach or suggest an inbred cucumber line, wherein the plants have a yellow flower, has resistance to angular leaf spot, anthracnose race 2, cucumber scab, powdery mildew and cucumber mosaic virus, and produce fruit that has a smooth surface, and a yellow, striped color.

### *Conclusion*

16. No claim is allowed.

17. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Anne R. Kubelik, whose telephone number is (703) 308-5059. The examiner can normally be reached Monday through Friday, 8:30 am - 5:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Amy Nelson, can be reached at (703) 306-3218. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 872-9306 for regular communications and (703) 872-9307 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the patent analyst, Kimberly Davis, at (703) 305-3015.

Anne R. Kubelik, Ph.D.  
January 27, 2003



AMY J. NELSON, PH.D.  
SUPERVISORY PATENT EXAMINER  
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